-Remarks-

Amendments

Entry of the above amendments and reconsideration and withdrawal of the rejection of the subject matter of Claims 46 - 50, 52 - 63 and 69 is respectfully requested. Applicants have amended Claims 47, 48, 52, 59, 60 and 69 hereinabove. Claims 64 and 65 have been canceled hereinabove. All amendments and cancellations have been made without waiver or prejudice. Applicants reserve the right to file continuation applications directed to any subject matter canceled herein.

The 35 U.S.C. §112, first paragraph, written description rejection of Claim 46.

The Examiner has rejected Claim 46 under 35 U.S.C. §112, first paragraph for allegedly containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor, at the time the application was filed, had possession of the claimed invention. Specifically, the Examiner has alleged that there is no support for the proviso in Claim 46. Applicants respectfully traverse.

The function of the written description requirement is to ensure that the inventor had possession, as of the filing date of the application relied on, of the specific subject matter claimed. *In re Edwards*, 196 USPQ 465 (CCPA 1978), citing *In re Blaser*, 194 USPQ 111 (CCPA 1977). Applicant is not required to describe the invention *in ipsis verbis*. *In re Edwards*, 196 USPQ 465 (CCPA 1978) citing *In re Lukach*, 169 USPQ 795 (CCPA 1971). By the very nature of the inquiry under this statutory provision, each case turns on its own specific facts. *In re Edwards*, at 467. The test is whether the originally filed specification disclosure reasonably conveys to a person having ordinary skill in the art that applicant had possession of the subject matter later claimed. *In re Kaslow*, 217 USPQ 1089 (Fed. Cir. 1983) and *In re Edwards*, citing *In re Driscoll*, 195 USPQ 434 (CCPA 1977).

Applicants disclose, at page 9, lines 10 - 18, that X^5 in the compounds of Formula V can be a halogen, particularly F, Br or Cl, or an $-OCOX_7$, $-OSO_2X_7$ or $-SO_2X_7$. X_7 may be lower alkyl or aryl. The compounds where X^5 is $-OCOX_7$, $-OSO_2X_7$ or $-SO_2X_7$ can be

prepared from the corresponding compounds where X^5 is halo or from similar substrates according to methods well known to those of ordinary skill in the art. Further, at page 52, lines 3 - 10, Applicants disclose that halogen is preferred for X^5 in compounds of Formula V, i.e., compounds of Claim 46. These halogenated compounds comprise a major portion of the compounds within the scope of Claim 46 after addition of the proviso.

Applicants submit that the specification satisfies the written description requirement for Claim 46 as it is currently formulated. It is well established that an inventor may excise prior art from a claim and still satisfy the written description requirement. *In re Johnson,* 194 U.S.P.Q.187 (C.C.P.A. 1977). The proviso was added to Claim 46 to overcome the previously asserted and now withdrawn 35 U.S.C. §103(a) rejection, i.e., the proviso simply removes prior art from the scope of the original claim. No subject matter has been added to the claim, in fact, the claim is narrower than it was prior to the addition of the proviso. Applicants were "simply claiming less than the full scope of [their] disclosure, a perfectly legitimate procedure since it is for an inventor to decide what bounds of protection he will seek." (see *In re Wertheim* 191 U.S.P.Q. 90 (C.C.P.A. 1976)).

See also *In re Driscoll*, 195 USPQ 434 (CCPA 1977), which cites the following case:

Engineering Development Laboratories v. Radio Corp. of America, 68 USPQ 238, 241-242 (CA2 1946).
Judge Learned Hand stated

> If, when [applicants] yield any part of what they originally believed to be their due, they substitute a new "invention", only two courses will be open to them: they must at the outset either prophetically divine what the art contains, or they must lay down a barrage of claims, starting with the widest and proceeding by the successive incorporation of more and more detail, until all combinations have been exhausted which can by any possibility succeed. The first is an impossible task; the second is a custom already more honored in the breach than in the observance, and its extension would only increase that surfeit of verbiage which has for long been the curse of patent practice, and has done much to discredit it. *It is impossible to imagine any public purpose which it could serve. [emphasis added]*

The Examiner has cited *Ex parte Graselli* for the proposition that a negative limitation still requires a written description. The only way for Applicants to have avoided adding a proviso would have been for Applicants to "lay down a barrage of claims, starting with the widest and proceeding by the successive incorporation of more and more detail, until all combinations have been exhausted which can by any possibility succeed." This is clearly what Judge Hand stated above would not serve "any public purpose." The description of the compounds within the current scope of the Claim 46 is clearly in the specification. That some of the compounds have been eliminated from the original broad scope does not alter the fact that the other compounds within the genus have been described. Accordingly, Applicants submit that the specification "reasonably convey[s] to persons skilled in the art that, as of the filing date thereof, the inventor had possession of the subject matter later claimed." *In re Edwards*, citing *In re Driscoll*, 195 USPQ 434 (CCPA 1977).

Applicants respectfully request that the Examiner reconsider and withdraw the 35 U.S.C. §112, first paragraph, written description rejection of Claim 46.

The 35 U.S.C. §112, first paragraph, enablement rejection of Claims 52, 60, 62, 64 and 65.

The Examiner has rejected Claims 52, 60, 62, 64 and 65 under 35 U.S.C. §112, first paragraph, as allegedly failing to comply with the enablement requirement. Specifically, the Examiner has alleged that claims 52, 60 and 62 are not enabled because a person skilled in the art cannot say for sure which diseases are embraced. Applicants submit that a skilled person would be quite clear as to which diseases are embraced by claims 52, 60 and 62, after amendment.

Claim 52 is directed to a method of treating any condition or complaint mediated by inhibition of a phosphodiesterase IV receptor. This is enabled in the specification at page 132, line 5 to page 133, line 4, wherein Applicants disclose assays for determining that the compounds of the instant invention are PDEIV inhibitors. Further, Applicants disclose at page 1, lines 7 - 9, that PDEIV inhibitors are useful as anti-inflammatory agents, antiallergic agents, bronchodilators, anti-asthmatic agents and as TNFα inhibitors. Further, Applicants disclose at page 1, lines 33 - 35, that PDE4

receptors have been identified in many tissues within the central nervous system, the heart, the vascular endothelium, the vascular smooth muscle and the aerial pathways, myeloid lines and lymphoid lines. Further, Applicants disclose at page 2, lines 7 and 8, that PDE4 inhibitors bring about bronchorelaxation by reducing the tonus of the smooth muscle fibrers in the aerial pathways. Further, Applicants disclose at page 1, line 36 to page 2, line 2, that PDE4 inhibitors, by increasing cAMP in cells involved in inflammation, inhibits their activation resulting in inhibition of the synthesis and release of mediators in mastocytes, monocytes, polymorphonuclear eosinophils and basophils, inhibition of chemotaxis and degranulation of polymorphonuclear neutrophils and eosinophils and inhibition of the proliferation and differentiation of lymphocytes. Further, Applicants disclose at page 2, lines 9 - 14, that PDE4 inhibitors treat chronic obstructive pulmonary disease (COPD), including chronic bronchitis and emphysema.

Claim 60, after amendment, is directed to methods of treating diabetes, acute respiratory distress syndrome (also known as ARDS) or acute pancreatitis. These conditions are well known conditions. The methods set forth in the specification clearly enable treatment of these conditions. See, e.g., the specification at page 45, lines 8 - 17 and page 132, line 5 to page 133, line 4.

Claim 62 is directed to methods of treating rheumatoid arthritis or multiple sclerosis. These conditions are well known conditions. The methods set forth in the specification clearly enable treatment of these conditions. See, e.g., the specification at page 45, lines 8 - 17 and page 132, line 5 to page 133, line 4.
Further, Applicants disclose, at page 48, line 15 to page 49, line 35, modes of administration which are to be used in the methods of Claims 52, 60 and 62 and all of the methods of this invention.

The Examiner has further alleged that the specification does not provide enablement for the treatment of cancer generally. Applicants have canceled claims 64 and 65 herein, rendering this rejection moot.

Applicants submit that Claims 52, 60 and 62 are enabled by the specification and respectfully request that the Examiner reconsider and withdraw the 35 U.S.C. §112, first paragraph, rejection thereof.

The 35 U.S.C. §112, second paragraph, rejection.

The Examiner has rejected Claims 47 - 50 under 35 U.S.C. §112, second paragraph for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

(i) The Examiner has alleged that claims 47 and 48 define the variable A_1 but do not have that variable present. Applicants have deleted the definition of A_1 in both claims.

(ii) The Examiner has stated that the phrase "such as" renders claims 59 and 60 indefinite because it is unclear whether the limitations following the phrase are part of the claimed invention. Applicants have amended claims 59 and 60 to remove the phrase "such as" therefrom.

(iii) The Examiner has stated that it is unclear in claim 52 which condition or complaint is mediated by inhibition of a phosphodiesterase receptor. Applicants have amended claim 52 so that it is clear that it is a phosphodiesterase IV receptor which is mediated. Applicants submit that this claim is accordingly limited to any condition or complaint mediated by the inhibition of a PDEIV receptor by a compound of Claim 35.

(iv) The Examiner has stated that in claim 60 it is not clear which diseases are associated with a high level of TNF-α. Applicants have amended claim 60 so that the phrase "high level of TNF-α" is no longer a limitation.

(v) The Examiner has suggested that Applicants use the American spelling of the word "septicemia" in claim 69 rather than the English spelling. Applicants have amended claim 69 to accommodate the Examiner's request.

The Examiner has also requested clarification whether "multiple organ failure syndrome" is treatable by a single drug. Applicants confirm that, according to this invention, multiple organ failure syndrome is treatable by a single compound from within the scope of claim 35.

Applicants respectfully request that the Examiner reconsider and withdraw the 35 U.S.C. §112, second paragraph, rejection of Claims 47 - 50, as amended.

-Conclusion-

Applicants, having responded to all points and concerns raised by the Examiner, believe this application to be in condition for allowance. An early and favorable action is respectfully requested.

Respectfully submitted,

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